UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	:	
	:	
v.	:	**Criminal No.** 1:20CR00046
	:	
BRIAN MICHAEL PARKS	:	**Violations:** **21 U.S.C. §§ 331(d); 333(a)(2)**
	:	
and	:	
	:	
MEDFIT SARMACUTICALS INC.	:	
(formerly known as MEDFITRX, INC.)	:	

INFORMATION

INTRODUCTION

1. Brian Michael Parks ("Parks") is a North Carolina resident and United States citizen.

2. MedFitRX, Inc. was a North Carolina company incorporated by Parks on or about March 25, 2016, with its principal place of business in North Carolina. Parks incorporated MedFitRX for the purpose of illegally distributing drugs, including Selective Androgen Receptor Modulators ("SARMs"), as purported dietary or sports supplements throughout the United States. MedFitRX was administratively dissolved on June 24, 2019, and reincorporated as MedFit Sarmacuticals Inc. on or about September 13, 2019, and is wholly owned by Parks.

3. MedFit Sarmacuticals Inc. and its predecessor, MedFitRX, Inc. are collectively referred to as "MedFitRX." Parks and MedFitRX are collectively referred to as "the Defendants."

4. The Food and Drug Administration ("FDA") of the United States Department of Health and Human Services regulates the manufacture, distribution, and marketing of all drugs shipped or received in interstate commerce through enforcement of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 301, *et seq.* ("FDCA"). The requirements of the FDCA, in part, are

meant to ensure that drugs sold for human use are safe and effective and bear labeling that contains accurate and adequate information.

5. The FDCA defines a "drug" in relevant part, as (1) any article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animal; (2) any article (other than food) intended to affect the structure or any function of the body; or (3) any article used as a component of either. 21 U.S.C. § 321(g). Whether an article is a drug is determined by its intended use, which is defined as "the objective intent of persons legally responsible for the labeling of drugs." The intent is determined by "such person's expressions or may be shown by the circumstances surrounding the distribution of the article." Such intent may be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. 21 C.F.R. § 201.128.

6. Some drugs are also "new drugs", which are defined as any drugs the composition of which is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. 21 U.S.C. § 321(p). It is a prohibited act for any person to introduce or deliver for introduction or to cause the introduction into interstate commerce of any new drug unless it has been the subject of a new drug application approved by FDA. 21 U.S.C. § 331(d), 355(a). There is no scienter required for a misdemeanor violation, and for a felony the violation must have been done with the intent to defraud or mislead. 21 U.S.C. § 333.

7. Selective Androgen Receptor Modulators are synthetic chemicals designed to mimic the effects of testosterone and other anabolic steroids. Products containing SARMs are often marketed and sold for body-building purposes, i.e. to increase muscle mass. FDA issued a public safety alert in 2017 warning consumers about ingesting products containing SARMs

because these products had been linked to life-threatening reactions, including liver toxicity, and that these products have the potential to increase the risk of heart attack and stroke.

8. From March 2016 to September 2019, Parks imported SARMs and other drug ingredients from China to his business in North Carolina; created, bottled, and labeled drug products with MedFitRX trade names in North Carolina and Ohio; marketed these drugs to those in the body-building or fitness community; and distributed these MedFitRX products in interstate commerce from North Carolina to places throughout the United States. At all relevant times, Parks was authorized to act on behalf of MedFitRX to conduct these activities.

9. Between June 2017 and September 2019 in particular, the Defendants regularly introduced unapproved new drugs into interstate commerce with the intent to mislead and defraud the FDA and consumers by: (1) misrepresenting MedFitRX drugs as "dietary supplements" or "sports supplements" rather than drugs; (2) failing to indicate the ingredients of MedFitRX products to create the impression that the products were safe and legal to use; (3) falsely claiming MedFitRX was "licensed" and "registered" to sell SARMs; and (4) importing MedFitRX drug ingredients in a way designed to avoid the regulatory scrutiny of the United States Government. The Defendants knew these products were drugs that were not approved and had not been subjected to the FDA's new drug application process. The Defendants distributed these drugs from North Carolina to Ohio, and subsequently to retail outlets and individual consumers throughout the United States who purchased the drugs over the internet, including consumers in the Western District of Virginia.

10. Defendants introduced and delivered for introduction, and caused the introduction or delivery for introduction into interstate commerce of, the following new drugs on or about the dates indicated below:

"On or About" Date of Invoice or Shipment	**Invoice Number**	**MedFitRX Product Trade Name**	**Active ingredients**	**Shipped From**	**Shipped To**
June 1, 2017	10046	Hexadrone	Hexadrone	Chillicothe, Ohio	Western District of Virginia
June 1, 2017	10046	Black Magic	LGD-4033; methyl-1-etiocholenolol	Chillicothe, Ohio	Western District of Virginia
September 14, 2017	10096	Winswole	Methylstenbolone	Chillicothe, Ohio	Western District of Virginia
September 14, 2017	10096	Alphadrolone	Methyl-1-Etiocholenolol-Epietiocholanolone	Chillicothe, Ohio	Western District of Virginia
April 27, 2018	3861	Trestolone	Trestolone	Chillicothe, Ohio	Western District of Virginia
April 27, 2018	3861	DMAXXX	Dimethazine	Chillicothe, Ohio	Western District of Virginia
April 27, 2018	3861	Kong	MK-2866 (Ostarine, CAS # 841205-47-8); GW501516 (CAS# 317318-70-0); MK677(lbutamoren, CAS # 159634-47-6); LGD4033 (Ligandrol, CAS # 1165910-22-4); RAD140 (CAS # 1182367-47-0)	Chillicothe, Ohio	Western District of Virginia
September 5, 2018	5541	King	1-Dehydromethandrostenolone; Tamoxifen; Methylclostebol; Methylstenbolone; Epiandrosterone; Trestolone Acetate Dimethazine Methylandrostanediol ; Mestanolone; Methylandrostanol	Chillicothe, Ohio	Western District of Virginia
September 5, 2018	5541	Kong	LGD-4033; Ostarine (MK-2866); lbutamoren (MK-677); RAD140 GW501516; Dimethazine	Chillicothe, Ohio	Western District of Virginia
September 5, 2018	5541	Black Magic	LGD-4033; Methoxydienone; Methylclostebol; RAD140; GW501516; Dimethazine	Chillicothe, Ohio	Western District of Virginia

11. Additionally, on or about May 17, 2018, Parks sold two MedFitRX products to undercover FDA Office of Criminal Investigation agents posing as consumers. The first product, Lucky SARMS Magical AF, contained the drugs S-23 and SR9009. The second product, Estrovert, contained the anabolic steroid drug Methyldienolone, a controlled substance prohibited under the Designer Steroid Control Act, 21 USC § 802(41). Defendants purchased these drugs from other countries and imported them to North Carolina to be manufactured into finished drug products for distribution across the United States.

12. The labeling associated with all of the above MedFitRX products indicated that they were drugs under 21 U.S.C. § 321(g)(1) in that the products claimed to affect the structure or function of the body. The above MedFitRX products also were new drugs that required FDA approval before they could be lawfully distributed in interstate commerce. The FDA had never approved the MedFitRX products identified above.

13. As early as October 2016, Parks was aware that at least some drugs in the above-listed MedFitRX products could cause severe health issues, including liver toxicity that could lead to the need for a liver transplant.

14. Parks knowingly took steps to mislead and defraud the Government in the sale of the above MedFitRX drugs. Parks knew the drugs in the above MedFitRX products were subject to scrutiny by Government law enforcement agencies, including the FDA and United States Customs and Border Protection. Parks, in an effort to avoid this law enforcement scrutiny, did not register MedFitRX with the FDA when he incorporated it in 2016. On about May 4, 2019, Parks also worked with other MedFitRX employees to hide MedFitRX products and drug manufacturing activity from an FDA inspection of another company he owned, Musclegen Research Inc., which was located at the same location as MedFitRX.

15. Parks worked with others to conceal the importation of the drugs used to manufacture the above MedFitRX products as they were shipped from China to North Carolina. On or about January 8, 2018, Parks imported the drug ingredients MK677, S-4, MK-2866, GW-501516, LGD-4033, and RAD-140 disguised and misdeclared as "biscuit mix powder," "corn powder," "grain mix powder," "bread mix powder," and "milk tea powder," respectively.

16. Parks also falsely claimed the MedFitRX products were for "research purposes only" on his website even though he intended that they be ingested by humans as ingredients in MedFitRX products. In one instance, on or about May 9, 2018, Parks told a prospective consumer that he could "not advise on dosages" for MedFitRX SARMs products, but then directed the consumer to a website that Parks controlled, SaRmsAndPros101.com, "to help with dosages."

17. Parks knowingly misled FDA and consumers about MedFitRX products. Parks knowingly marketed the above MedFitRX products as "dietary supplements" and "sports supplements" to create the impression they were safe and legal to use, and otherwise intentionally failed to include certain drug ingredients on the product labels. Parks also falsely claimed on numerous occasions to prospective customers that the FDA had given him the authority to sell SARMs. On or about November 11, 2017, Parks claimed to a prospective customer that MedFitRX "had an internal legal council [sic] as well as insurance reviews quarterly in order to maintain our registration with the FDA[.]" In another instance, on or about May 17, 2018, Parks falsely told undercover FDA Special Agents posing as prospective customers that his company was "the only manufacturer in the U.S. that is licensed, registered, and insured to make pro-hormones and SARMs so that's what you'll see in these smaller bottles … without stepping over the legal-illegal line." Parks had not registered MedFitRX with the FDA, nor was there any "license" he could obtain that would make his activity legal.

18. During the period of 2016 to present, the Defendants distributed a quantity of the above drug products worth more than $1,189,245.36.

COUNT I

Introduction of Unapproved New Drugs into Interstate Commerce
21 U.S.C. §§ 331(d), 333(a)(2), and 355

The United States Attorney charges that:

19. The Introduction is realleged and incorporated by reference.

20. From on or about June 1, 2017, through on or about May 17, 2018, BRIAN MICHAEL PARKS and MEDFIT SARMACUTICALS INC. (formerly known as MedFitRX, Inc.), with the intent to defraud and mislead, caused the introduction and delivery for introduction into interstate commerce of quantities of new drugs that FDA had not approved for distribution in the United States, from various locations outside the state of Virginia to various locations in the Western District of Virginia and elsewhere.

21. BRIAN MICHAEL PARKS used his business entity, MEDFIT SARMACUTICALS INC. (formerly known as MedFitRX, Inc.), to cause the interstate distribution of new drugs throughout the United States and elsewhere.

22. All in violation of 21 U.S.C. §§ 331(d), 355, and 333(a)(2).

NOTICE OF FORFEITURE

23. Upon conviction of the offense alleged in this Information, BRIAN MICHAEL PARKS and MEDFIT SARMACUTICALS INC. (formerly known as MedFitRX, Inc.), shall forfeit to the United States any unapproved new drugs, pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461, that were shipped to various locations in the Western District of Virginia and elsewhere.

24. Because the above-described forfeitable property has been transferred and sold to third parties and cannot be located upon the exercise of due diligence, the property to be forfeited

to the United States includes a forfeiture money judgment in the amount of $1,189,245.36 in U.S. currency pursuant to 21 U.S.C. § 853(p).

DATED: November 23, 2020

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